

Humane Restraint

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TAB F: 510(k) Summary of Safety and Effectiveness

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Date summary was prepared: August 28, 1996

Device name:

Trade name(s): Silicone Rubber Cuff
Fleece Liner
Web Torso Restraint
Nylon Limb Holder
Vinyl Limb Holder
Nylon Bed Restraint (wrist)
Nylon Torso Restraint
Nylon Transporter

Common name: Same

Classification name: Protective Restraint

Predicate device:

The fleece liners, silicone rubber cuffs, web torso restraints, nylon limb holders, vinyl limb holders, nylon bed restraints (wrist), nylon torso restraint, and nylon transporter, all legally marketed at this time. The devices described in this submission *are* our currently marketed products. This submission is in response to 61 FR 8431 -8439, Protective Restraints; Revocation of Exemptions From the 510(k) Premarket Notification Procedures and Current Good Manufacturing Practice Regulations.

Device Description:

- a. Silicone Rubber Cuff The device is made of silicone rubber molded over a 0.015 inch mylar insert. A nickel plated oblong shaped steel loop is riveted on one end that can be inserted into one of 5 slots on the other end as the first step in securing

the device to a wrist or ankle and is secured using leather belts slipped through the metal loop and attached to a bed, a leather waist belt or to a cuff on the opposite wrist or ankle (for ambulatory restraint). The leather belts are usually sold separately and have been marketed for more than 100 years by the Humane Restraint Company. The cuff is may be covered with an optional polyester fleece liner to reduce chafing; is usually sold separately. The cuff is 3" wide and available in two lengths, 15" for the wrist and 15" for the ankle. The size is adjustable depending on which slot the steel loop is place through. (Note: The silicone rubber cuff is available as part of a kit with the optional belts (all pre-amendment) and disposable fleece liner.)

- b. Disposable Fleece Liner. This is an accessory to reduce chafing when used as a cover for the silicone rubber cuff or our leather cuff of essentially the same design. (The leather cuff has been marketed by Humane Restraint for more than 100 years) The fleece liner is 3-1/2 inches wide and available in two lengths 7-1/2 and 9-1/2 inches to correspond with the cuff sizes available. The cuff is made of polyester fleece with two strips of elastic sewn to the back, to secure the liner when slipped over the cuff.

- c. Web Torso Restraint. The 2" polypropylene webbing torso restraint is available in three sizes: (Small = 24 - 36", Medium = 30 - 42", and Large = 36 - 38"). The web torso restraint attaches to the bed frame with either a sewn on L-400 lock or a sewn-on 2" polyethylene side-release buckle with 2" polyethylene slide bar each attached 36" from the end. The person to be restrained is place on top of the restraint and secured with the torso strap. These restraints are intended to secure a severely agitated person to a bed and are optional for use with limb restraints to prevent a person from sitting up in bed.

- d. Nylon limb Holder. The cuffs are 2" wide nylon webbing available in two lengths, 12" for wrist and 14" for ankle. The wrist cuff is red and the ankle cuff is black. The limb cuff is fleece-lined and double secured with a sewn on 4" piece of 1-1/2" hook and loop closure and a sewn on metal locking closure (L-400 lock). A 2" by 48" nylon webbing strap with the same type lock is sewn onto the cuff for attachment to a bed frame.

- e. Vinyl Limb Holder. The cuffs are 2" x 19" polyester fleece fused to perforated vinyl. A 2" wide nylon webbing strap with 1-1/2" x 4" sewn on piece of hook and loop closure is sewn on to the outside surface of the cuff. Two types of closures are available, a L-400 lock sewn on to the nylon webbing or sewn-on web buckle attached to the outside of the perforated vinyl to secure the cuff to the wrist. A 2" x 46" nylon webbing strap slips through the cuff closure perpendicular to the cuff webbing for attachment to a bed frame.

- f. Nylon Bed Restraints (Wrist): The device is attached to the bed frame using a 2" x 12 foot nylon webbing strap with either two sewn on L-400 lock or two sewn-on 2" polyethylene side-release buckle with 2" slide bar, each attached 38" from each end. Two 2" x 12" (wrist) or two 2" x 14" (ankle) fleece-lined cuffs are sewn on to the 64" length of nylon webbing each either 14" (wrist) or 9" (ankle) from the center. The cuffs are available with a choice of 4 different types of closures: a 1" polyethylene side release buckle with 1" polyethylene slide bar, an L-400 lock, a 1 1/2" double D ring buckle, or a polypropylene web buckle.
- g. Nylon Torso Restraint: A 2" x 96" nylon webbing torso restraint is available in one size. The restraint is place over the chest or upper legs and secured to a bed with either two L-400 lock buckles or two 2" polyethylene side-release buckle, each sewn 28" from the end. The restraint is optional for use with wrist restraints to prevent the restrained person from sitting up in the bed.
- h. Nylon Transporter: This device consists of a 2" x 64" nylon webbing waist belt with two 2" x 12" nylon webbing wrist cuffs sewn on, the first 9" from the keeper, the second, 13" from the first. The waist belt is secured in back with a 2" polyethylene side release lock with 2" slider bar; the wrist cuffs are double secured with 4 1/4 inches of 1-1/2" hook and loop closure and twin D rings sewn onto the cuff along with a 1" x 18" black nylon webbing strap to cinch the D rings.

Intended Use:

Other than the fleece liner, all devices are intended to limit movement of severely agitated persons who may cause harm to themselves or to others if not restrained. The fleece liner is an accessory to reduce chaffing when used with the silicone rubber cuff. Where locks are a part of the device, they are for the purpose of lessening the chance of unauthorized release.

The following chart describes the device applications.

Indications for use (continued)

DEVICE	LOCKS		APPLICATION					NOTES	CATALOG PAGE #
	WITH	WITH OUT	AMBULATORY		BED				
			WRIST TO WRIST	ANKLE TO ANKLE	WRIST TO BED	ANKLE TO BED	TORSO TO BED		
Silicone Rubber Cuff*	N/A	N/A	X	X	X	X		To be used with locking or non-locking leather belts (pre-1976) and torso and/or chest restraints and/or optional fleece liners **	2
Web Torso Restraint	X	X					X (waist)	Optional use with limb holders	12
Nylon Limb Holder	X				X	X		Optional use with chest or torso restraints	9
Vinyl Limb Holder	X	X						Optional to use with chest or torso restraints	9
Nylon Bed Restraints	X	X			X	X		May be used with optional nylon chest restrain	9
Nylon Torso Restrain	X	X					X (chest and upper leg)	Optional to use with nylon bed restraint system	9
Nylon Transporter		X	X	X					15

* The silicone rubber cuff is available in kit form with belts and fleece liners listed under "Notes"

** Fleece liner is an accessory to cover leather and silicone rubber wrist cuffs to reduce chafing

Comparative information:

The devices used for comparative purposes are exactly the same as devices currently marketed by the Humane Restraint Company and as described in this submission.

These devices are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are legally marketed by the Humane Restraint Company as of the date of this submission. The Humane Restraint Company has been manufacturing and commercially distributing these devices for the number of years as follows:

DEVICE	YEARS
Silicone Rubber Cuff	1
Disposable Fleece Liner	1
Web Torso Restraint	19
Nylon Limb Holder	1
Vinyl Limb Holder	4
Nylon Bed Restraint (wrist)	4
Nylon Torso Restraint:	4
Nylon Transporter	5

In addition to the devices listed and described in this submission, the Humane Restraint Company has been marketing devices with similar in designs but using *different materials* for more than 20 years. We have had no reports of injury for any of our products.

These restraint are intended and labeled for prescription use. The devices are not intended for lay use. The health care facilities where our devices are used are subject to the Health Care Financing Administration (HCFA) rules and usually meet accreditation standards. HCFA rules governing appropriate use of these devices and accreditation standards specifying conditions for device use and required personnel training provide controls necessary to ensure that the devices are used correctly. The application of these standards along with public awareness, and health care provider training have contributed significantly to ensuring that the least restrictive restraint is used, that restraints are used only when needed for proper medical treatment, and that their use is under appropriate supervision.

Use Restrictions for Restraints

The use of all patient restraints is subject to Health Care Financing Administration's Regulations which prohibit the use of any restraint, physical or chemical, imposed for the purpose of discipline or convenience and specify that the patient situation be evaluated to assure that the least restrictive restraint is used.

Accreditation Training Requirements

Further, the "Revised Standards for Restraint and Seclusion", TX.7.1.3.2.4, 1996 Accreditation Manual for Hospitals, Volume 1, Joint Commission on Accreditation of Healthcare Organizations apply to all organizations accredited under the 1996 AMH, Volume 1, the Comprehensive Accreditation Manual for Ambulatory Care, and the Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation-Developmental Disabilities.

These standards require that restraint be used correctly by competent trained staff. Organizations must identify, educate and determine competency of those staff members who apply or remove restraints and that the training consist of frequently repeated in-service education, including an understanding of manufacturers instructions for use of restraint device.